

§ 862.1680 Testosterone test system.

(a) *Identification.* A testosterone test system is a device intended to measure testosterone (a male sex hormone) in serum, plasma, and urine. Measurement of testosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.

(b) *Classification.* Class I.

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§ 862.1685 Thyroxine-binding globulin test system.

(a) *Identification.* A thyroxine-binding globulin test system is a device intended to measure thyroxine (thyroid)-binding globulin (TBG), a plasma protein which binds thyroxine, in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

(b) *Classification.* Class II.

§ 862.1690 Thyroid stimulating hormone test system.

(a) *Identification.* A thyroid stimulating hormone test system is a device intended to measure thyroid stimulating hormone, also known as thyrotrophin and thyrotrophic hormone, in serum and plasma. Measurements of thyroid stimulating hormone produced by the anterior pituitary are used in the diagnosis of thyroid or pituitary disorders.

(b) *Classification.* Class II.

§ 862.1695 Free thyroxine test system.

(a) *Identification.* A free thyroxine test system is a device intended to measure free (not protein bound) thyroxine (thyroid hormone) in serum or plasma. Levels of free thyroxine in plasma are thought to reflect the amount of thyroxine hormone available to the cells and may therefore determine the clinical metabolic status of thyroxine. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

(b) *Classification.* Class II.

§ 862.1700 Total thyroxine test system.

(a) *Identification.* A total thyroxine test system is a device intended to measure total (free and protein bound) thyroxine (thyroid hormone) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

(b) *Classification.* Class II.

§ 862.1705 Triglyceride test system.

(a) *Identification.* A triglyceride test system is a device intended to measure triglyceride (neutral fat) in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of patients with diabetes mellitus, nephrosis, liver obstruction, other diseases involving lipid metabolism, or various endocrine disorders.

(b) *Classification.* Class I.

§ 862.1710 Total triiodothyronine test system.

(a) *Identification.* A total triiodothyronine test system is a device intended to measure the hormone triiodothyronine in serum and plasma. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases such as hyperthyroidism.

(b) *Classification.* Class II.

§ 862.1715 Triiodothyronine uptake test system.

(a) *Identification.* A triiodothyronine uptake test system is a device intended to measure the total amount of binding sites available for binding thyroid hormone on the thyroxine-binding proteins, thyroid-binding globulin, thyroxine-binding prealbumin, and albumin of serum and plasma. The device provides an indirect measurement of thyroxine levels in serum and plasma. Measurements of triiodothyronine uptake are used in the diagnosis and treatment of thyroid disorders.

(b) *Classification.* Class II.

§ 862.1720 Triose phosphate isomerase test system.

(a) *Identification.* A triose phosphate isomerase test system is a device intended to measure the activity of the enzyme triose phosphate isomerase in erythrocytes (red blood cells). Triose